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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY, DOCKET NO.
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09/298,358 04/23/99 BLATT

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EXAMINER

NGUYEN, P

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

03/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/298,358

(s)

Blatt et al

Examiner

Bao-Thuy L. Nguyen

Group Art Unit

1641



☒ Responsive to communication(s) filed on 4/23/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to by the draftsman. See attached PTO-948 for more information. Correction is required.

Claim Rejections - 35 USC § 112

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear exactly what is being claimed, i.e. what chemical reagent(s) is present in the device and where they are located with respect to one another.

Claim 1 is confusing because "the clean" lacks antecedent support. For the purpose of examination on the merit, "the clean" is interpreted as an equivalent of the sample that has been applied to the sample receptor.

Claim 1 is further confusing because it is unclear what is meant by "chemical reagent corresponding to an assay". It is also unclear what is meant by "corresponding". For the purpose of examination on the merit, this phrase is interpreted as chemical reagent corresponding or specifically binding to an analyte.

For the purpose of examination on the merits, claim 1 is interpreted as a device having a sample receiving receptor located on the exterior surface of a device housing, the sample receiving receptor is connected to a transport matrix. The transport matrix comprising at least one chemical reagent located in a detection zone for specifically binding with the analyte to form a reaction product.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 24 of U. S. Patent No. 5,968,839 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant invention and '839 both claim a diagnostic device comprising a housing having an exterior surface, a receptor configured to receive the sample, and at least one transport matrix for reacting the sample with a capture reagent to yield a detectable change in a detection area.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application

which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

6. Claim 1 is rejected under the judicially created doctrine of double patenting over claims 1 and 10 of U. S. Patent No. 5,945,345 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant invention and '345 both claim an immunoassay device comprising a housing having an exterior surface, a sample receptor means for receiving the sample, and a transport matrix having a detection zone yielding a physically detectable change which correlates with the amount of analyte.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Blatt et al (WO 97/20207)

Blatt et al disclose a device for determining the presence of at least one of a plurality of analytes in a sample of whole blood. The device includes a housing having an exterior surface and a sample receptor means for receiving the sample of whole blood containing an analyte selected for determining its presence. The sample receptor means is located on the exterior surface of the housing. A filter receives the sample of whole blood from the sample receptor means. The filter has a solid phase support and an agglutinin for red blood cells. A sample treatment means reacts the sample of plasma with a reagent to yield a physically detectable change which correlates with the amount of the selected analyte in the sample of plasma. See page 5, second paragraph.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by May et al (WO 88/08534).

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device containing a labeled specific binding reagent for an analyte which labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). May teaches an embodiment of the invention in which a dry porous nitrocellulose carrier communicates indirectly with the exterior of the casing via a bibulous urine receiving member which protrudes from the casing and which can act as a reservoir from which urine is released into the porous carrier (page 7, lines 23-29, see also figure 9 and description on page 23). The device also contains a control zone which is loaded with an antibody that will bind to the labeled antibody from the first zone. The control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte which will react with excess labeled reagents from the first zone (page 9). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). May teaches a plurality of detection zones arranged in series on the porous

solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (page 11). Quantitative measurement may be done visually by eye or by instrument (page 10, lines 10-13). May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (page 13). May also teaches an absorbant sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (page 11, lines 1-17).

10. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Blatt et al (US Patent No. 5,968,839).

Blatt et al disclose a transport matrix producing a physically detectable change in a predetermined distribution across a detection zone which correlates with the amount of selected analyte in a sample. The matrix includes a detection zone having a capture reagent yielding a physically detectable change which correlates with the amount of selected analyte in the sample. The capture reagent is immobilized on the matrix in a predetermined distribution from the leading boundary to the trailing boundary of the detection zone. See column 2, line 64 through column 4, line 15. Blatt et al also disclose an embodiment where a receptor is configured to receiving the sample containing an analyte, the receptor is located on the exterior surface of the housing (column 3, lines 60-66).

11. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Blatt et al (US Patent No. 5,945,345).

Blatt et al disclose a filter for removing one or more substances from a sample including a housing defining an interior space. The housing has an inlet and an outlet to provide fluid communication between the interior space and the exterior of the housing. A solid phase support is immobilized within the interior space. The filter includes means for physically retaining the solid phase support within the housing and an active chemical component having an affinity for binding to and immobilizing the interfering substance. The active chemical component is

immobilized on the solid phase support and is insoluble in the sample. See column 2, lines 55-65. Blatt et al also disclose an embodiment where a sample receptor means for receiving the sample containing an analyte is located on the exterior surface of the housing (column 3, line 17-25).


Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday through Wednesday, from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Bao-Thuy Nguyen
Patent Examiner
Art Unit 1641